

## PMD94

# DELATED ENHANCEMENT CARDIAC MAGNETIC RESONANCE TO REFINE PATIENT SELECTION FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR THERAPY IN PRIMARY PREVENTION - AN EXPLORATORY COST-EFFECTIVENESS ANALYSIS

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**OBJECTIVES:** The majority of patients who get an implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death (SCD) never need to receive appropriate ICD therapies. Better risk-stratifying tools are thus needed to improve the cost-effectiveness of device implantation. The purpose of this study was to assess the cost-effectiveness of using delayed enhancement cardiac magnetic resonance (CMR) to refine patient selection for ICD therapy in primary prevention. **METHODS:** A Markov model was developed to assess long-term survival, quality-adjusted life years (QALYs), and lifetime costs for a cohort of patients with reduced left ventricular ejection fraction without previous ventricular arrhythmias. Two different strategies were compared: A) implant an ICD in all patients ("ICD for all"); and B) perform CMR and implant an ICD only in patients with delayed enhancement exceeding 5% of myocardial mass ("CMR-guided ICD"). Clinical and economic inputs were derived from European representative literature. **RESULTS:** The "ICD for all" strategy led to a total cost of €68,818 and 7.0 QALY per patient, implying an incremental cost of €7,372 and allowing a gain of 0.1 QALY when compared to the strategy "CMR-guided ICD". Consequently, the cost-utility ratio is €77,943 per QALY. Probabilistic sensitivity analysis showed that, assuming a willingness to pay of €50,000 per QALY, the "ICD for all" strategy would be cost-effective in 31% of the simulations. **CONCLUSIONS:** Results suggest that implanting ICD in selected patients allows to use this device in those that benefit most, improving the cost-effectiveness of ICD implantation for the primary prevention of sudden cardiac death.

## PMD95

# COST-EFFECTIVENESS ANALYSIS OF TESTING FOR BRCA1 AND BRCA2 MUTATIONS IN WOMEN DIAGNOSED WITH OVARIAN CANCER AND THEIR FEMALE FIRST- AND SECOND-DEGREE RELATIVES USING A DISCRETE EVENT SIMULATION: A UK HEALTH SERVICE PERSPECTIVE

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**OBJECTIVES:** Mutations in BRCA1 and BRCA2 genes are associated with an increased risk of breast and ovarian cancer. If a BRCA mutation is detected in women with ovarian cancer their unaffected relatives may be offered genetic testing and prophylactic surgery. The long-term cost-effectiveness of providing BRCA testing to women with ovarian cancer and to their unaffected female first-degree relatives in the UK has previously been evaluated using a lifetime Markov model, but the approach had a number of limitations. The current study will employ a hybrid discrete event simulation (DES) structure that addresses some of the Markovian limitations associated with the previous model and will differentiate between BRCA1 and BRCA2 mutations and will consider results for a number of possible UK family pedigrees. **METHODS:** A hybrid DES will be constructed with a lifetime horizon, to evaluate the cost-effectiveness of BRCA testing in women with ovarian cancer and their female first- and second-degree relatives versus no testing. The model will consider the incidence of ovarian and breast cancer, differentiating between those with BRCA1 and BRCA2 mutations, as well as the associated mortality rates. Individuals identified as BRCA1 or BRCA2 positive will be eligible to undergo bilateral mastectomy and bilateral salpingo-oophorectomy, which significantly reduce the risk of both ovarian and breast cancer. **RESULTS:** Results will be presented as an incremental cost-effectiveness ratio expressed as a cost per quality adjusted life year (QALY). These will be compared to the UK cost-effectiveness threshold of €20,000 per QALY gained. A number of sensitivity and subgroup analyses will be presented alongside the base case. **CONCLUSIONS:** We aim to demonstrate that screening patients with ovarian cancer and their first- and second-degree relatives for the BRCA1 and BRCA2 mutation is cost-effective and reduces the incidence of breast and ovarian cancer in the population.

## PMD96

# IDENTIFYING THE MOST COST-EFFECTIVE WAY OF DIAGNOSING ASTHMA IN ADULTS USING MULTIPLE TESTS – A COST-UTILITY ANALYSIS FROM THE NICE ASTHMA GUIDELINE

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**OBJECTIVES:** To develop an economic model to inform recommendations on the optimal diagnostic pathway for the recent clinical guideline on the diagnosis and monitoring of asthma, commissioned by the National Institute for Health and Care Excellence (NICE). **METHODS:** A de-novo economic model evaluated current practice alongside six diagnostic pathways comprising of the following tests: spirometry, bronchodilator reversibility (BDR), peak expiratory flow (PEF), fractional exhaled nitric oxide (FeNO) and methacholine/histamine challenge testing (MCT). A model was developed using a decision tree to identify what proportion of individuals would receive a correct (true positive, true negative) or incorrect (false positive, false negative) diagnosis, utilising diagnostic accuracy data in adults from systematic reviews conducted for each test. These proportions fed into one of four Markov models, depending on the diagnosis, which calculated final health and cost outcomes. The model explored the impact of alternative false diagnoses, such as chronic obstructive pulmonary disease, and applied modelling techniques to account for the effect of conditional dependence on diagnostic accuracies. **RESULTS:** The most cost-effective strategy at a £20,000 per/QALY threshold consisted of all individuals undergoing

spirometry, BDR and FeNO testing. Where diagnostic uncertainty remained, individuals would then undergo PEF and finally MCT testing. This strategy dominated other strategies that did not utilise MCT, producing higher health outcomes at a lower cost to the health service. Two strategies that made more individuals undergo MCT were not cost-effective at the threshold with incremental cost-effectiveness ratios of £20,276 and £32,565 per/QALY respectively. Although assumptions were made relating to conditional dependence and the consequences of false diagnoses, the model's results were found to be robust to significant changes in these and other uncertain parameters. **CONCLUSIONS:** These findings highlight the need for thorough objective testing for diagnosing asthma as doing so has the potential to improve health outcomes whilst reducing costs to the health service.

## PMD97

# RISK FACTORS FOR DEVELOPING DIABETES AS A DETERMINANT OF THE COST-EFFECTIVENESS OF USING CORONARY CALCIUM SCORE TO GUIDE PRIMARY PREVENTION WITH STATINS

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**OBJECTIVES:** The determination of coronary calcium score allows to identify individuals for which primary prevention with statins may be unnecessary. In this study it is shown that the presence of risk factors for developing diabetes interacts with the benefits of this identification. **METHODS:** A Markov model was used to estimate the evolution of two cohorts with elevated C-reactive protein and low LDL cholesterol: one without risk factors for developing diabetes and another with those risk factors. The progression of both cohorts was simulated assuming four alternative strategies: "no treatment", "treat if score>100", "treat if score>0" and "treat all". **RESULTS:** For individuals without risk factors for diabetes, the "treat all" strategy is the most expensive but allows to achieve better clinical outcomes, with a cost per QALY of €24,164 vs. the strategy "treat if score>0". For those with risk factors for diabetes, the strategy "treat all" remains the most expensive, but the decrease in coronary events does not compensate the increase in diabetes incidence, whereby the strategy "treat all" is dominated by "treat if score>0". The cost per QALY of this latter strategy in comparison to "treat if score>100" is €36,034. Deterministic and probabilistic sensitivity analysis show that results are robust. **CONCLUSIONS:** The presence of risk factors for diabetes affects the cost-effectiveness of using coronary calcium score as a guide to implement primary prevention in this population.

## PMD98

# EXAMINING THE ECONOMIC IMPACT OF LABORATORY DEVELOPED TESTING IN FLOW CYTOMETRY IMMUNOPHENOTYPING FOR HEMATOLOGIC MALIGNANCIES: AN ANALYSIS OF HEALTH RESOURCE UTILIZATION

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**OBJECTIVES:** Each year approximately 900,000 new cases of hematological malignancies are diagnosed globally. Diagnosis is comprised of multiple modalities, including flow cytometry. Current laboratory developed testing (LDT) for flow cytometry is non-standardized and error prone. Insufficient research has been published evaluating the cost and errors in this space. Manual work, including steps such as antibody selection, compensation, and pipetting have been identified as potential sources of error in flow cytometry. The aim of this study is to quantify the time and associated economic impact of manual work in a flow cytometry process for hematological malignancies. **METHODS:** An observational study was conducted at a public Canadian acute care clinical laboratory in collaboration with a lean specialist team for the purposes of workflow analysis. The results of this pilot were used to inform this extended costing analysis. Evaluation of the instrument, reagent, and sample preparation was performed. Total opportunities for error in the workflow were identified (defined as steps involving manual efforts) and manual labor time was then used to estimate indirect costs. **RESULTS:** A total of 37 steps were involved in instrument set-up, 81 steps for manual reagent and sample preparation, each of these steps containing multiple opportunities for error. At a 550 bed institution performing 591 leukemia and lymphoma tests annually, it was estimated that a total of 365 hours of manual labor by a skilled medical lab technologist incurred indirect costs of \$18,250. **CONCLUSIONS:** Based on this case study, manual work resulted in substantial cost to the laboratory in indirect costs. This suggests that in addition to reducing the potential for error, minimizing unnecessary manual steps in the flow cytometry workflow could also reduce laboratory indirect costs and improve efficiency. Future research is warranted to quantify the frequency of errors in manual steps in LDT for flow cytometry.

## PMD99

# ECONOMICAL AND ORGANIZATIONAL IMPACT OF ADOPTING DIFFERENT IN SITU HYBRIDIZATION TECHNOLOGIES TO ASSESS HER2 GENE AMPLIFICATION IN BREAST CANCER

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**OBJECTIVES:** Human epidermal growth factor receptor 2 (HER2) status identification is established by immunohistochemistry and in situ hybridisation (ISH). Silver in situ hybridisation (SISH) is an alternative technique to the fluorescence in situ hybridisation (FISH). Both methods are recommended by American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) 2013 guidelines. The primary aim of this analysis is to evaluate the economical and organizational impact by adopting FISH or SISH test for HER2 testing. **METHODS:** We conducted an analysis to evaluate costs, times (laboratory personnel working hours) and laboratory-space to process a sample using the manual method (FISH) compared to the automated system (SISH). The analysis was performed from the pathology laboratory's perspective. We analysed the complete workflow (laboratory personnel and medical resource used) to perform the two tests (FISH and SISH) during pathol-

ogy laboratory standard working days. The time required to test one sample was timed for each methodology separately and the pertaining costs were calculated. The working dimension of the two technologies and of the instruments needed was also measured. **RESULTS:** The hands-on time for SISH was 76.25% lower than the implementation of FISH and the dedicated spaces needed to carry out the SISH test was 45.27% less than FISH. Lastly, the costs of using an automated SISH system were lower than FISH. **CONCLUSIONS:** As a consequence of a significant reduction of laboratory personnel working hours, medical resources used and pathology laboratory spaces, the use of SISH technique to identify HER2 status is a cost-saving alternative to FISH from the perspective of the pathology laboratory.

#### MEDICAL DEVICE/DIAGNOSTICS – Patient-Reported Outcomes & Patient Preference Studies

##### PMD100

##### COPD ICS/LABA TREATMENT INHALERS AND THEIR IMPACT ON ADHERENCE

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**OBJECTIVES:** Chronic Obstructive Pulmonary Disease (COPD) is a chronic respiratory disease with a high burden of disease and a relevant Public Health problem. The active patient active involvement is crucial to yield the proper disease control. The aim of the study was to assess treatment adherence with the combination of inhaled corticosteroids (ICS) and long-acting beta-2 agonists (LABA), known as ICS/LABA, in the same fixed dose combination inhalers, depending on the inhaler device used: pressurized metered dose inhalers (pMDI) or dry powder inhalers (DPI), for the treatment of COPD in a real world background. Additionally COPD exacerbations, resources consumption, and associated costs were recorded. **METHODS:** An observational, retrospective study was performed. Patients aged  $\geq 40$  years, diagnosed with COPD, and who initiated an ICS/LABA combination treatment during 2007-2011. Patients follow-up lasted for 3 years. Two treatment groups of patients were identified and assessed, depending on the inhaler device used: pMDI or DPI. The main measures were: adherence (possession drug ratio), persistence, asthma severity, ICS/LABA combinations used, exacerbations, resources use and their costs (direct and indirect costs). Multivariate methods were used for the variables correction, with a p significance degree  $<0.05$ . **RESULTS:** We included 1,418 COPD patients. Mean age 72.1 years, 82.7% male: 594 patients (41.9%) received an pMDI and 824 patients (58.1%) received an DPI. Patients who used and pMDI device showed a higher treatment adherence (RPM: 83.3% vs 79.9%,  $p<0.05$ ), fewer number of exacerbations (40.1% vs 48.2%,  $p=0.002$ ), and a lower health cost (€3,943 vs €4,621,  $p<0.001$ ). **CONCLUSIONS:** Despite the limitations of the study, patients with COPD who started an ICS/LABA therapy who were treated with an pMDI device had higher adherence rates, better health outcomes and lower health costs for the Spanish National Health System.

##### PMD101

##### THE IMPORTANCE OF INHALER DEVICES: AN INCORRECT INHALER TECHNIQUE LEADS TO SUBOPTIMAL MEDICATION COMPLIANCE IN PATIENTS WITH COPD

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**OBJECTIVES:** This study aims to identify factors associated with poor compliance to COPD treatment in patients receiving a fixed-dose combination (FDC) of inhaled corticosteroids and long-acting  $\beta_2$ -agonist (ICS/LABA), focusing on the importance of inhaler devices. **METHODS:** We conducted a retrospective and multicentre study based on a review of medical registries between 2007-2012 of COPD patients ( $n=1,263$ ) treated with ICS/LABA FDC, whose medical devices were either dry powder inhalers (DPI) or pressurized metered-dose inhalers (pMDI). Medication compliance included persistence outcomes through 18 months and medication possession ratios. Data on exacerbations, comorbidities, demographic characteristics and healthcare resource utilization were also included as confounders of medication compliance. **RESULTS:** The analyses revealed that COPD patients whose medication was delivered by a DPI were less likely to comply with their treatment compared to patients with pMDI, after adjusting for confounding factors, especially active ingredients. Younger groups of patients were less likely to comply with their medication compared to the oldest group. Smoker men were less likely to comply with their medication compared to women and non-smokers. Comorbidities decreased the probability of treatment compliance. Those patients that visited their GP once a month were more likely to comply with their medication regimen, however sub-optimal compliance was more likely to occur among those patients who visited more than 3 times per month their GP. We also found that worsening of COPD is negatively associated with compliance. **CONCLUSIONS:** According to this study, inhaler devices influence patients' compliance for long-term COPD medication. We also found that DPIs delivering ICS/LABA FDC had a negative impact on medication compliance. Patients' clinic and socioeconomic characteristics were associated with compliance.

##### PMD102

##### DEVICE INHALATORS IN ASTHMA AND THEIR IMPACT ON TREATMENT ADHERENCE

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**OBJECTIVES:** Asthma is a chronic respiratory disease with a high burden of disease and a relevant Public Health problem. The active patient active involvement is crucial to yield the proper disease control. The aim of the study was to assess treatment adherence with the combination of inhaled corticosteroids (ICS) and long-acting beta-2 agonists (LABA), known as ICS/LABA, in the same fixed dose combination inhalers, depending on the inhaler device used: pressurized metered dose inhalers (pMDI) or dry powder inhalers (DPI), for the treatment of asthma in a real world background. Additionally asthma exacerbations, resources consumption, and associated costs were recorded. **METHODS:** An observational, retrospective study was performed. Patients aged  $\geq 18$  years, diagnosed with asthma, and who initiated an ICS/LABA combination treatment during 2007-2011. Patients follow-up lasted for 3 years. Two treatment groups of patients were identified and assessed, depending on the inhaler device used: pMDI or DPI. The main measures were: adherence (possession drug ratio), persistence, asthma severity, ICS/LABA combinations used, exacerbations, resources use and their costs (direct and indirect costs). Multivariate methods were used for the variables correction, with a p significance degree  $<0.05$ . **RESULTS:** We included 2,082 asthma patients. Mean age 52.6 years, 65.3% female: 566 patients (27.2%) received an pMDI and 1,516 patients (72.8%) received an DPI. Patients who used and pMDI device showed a higher treatment adherence (RPM: 82.9% vs 80.8%,  $p<0.05$ ), fewer number of exacerbations (17.7% vs 24.9%,  $p<0.001$ ), and a lower health cost (€2,531 vs €3,020,  $p<0.001$ ). **CONCLUSIONS:** Despite the limitations of the study, patients with asthma who started an ICS/LABA therapy who were treated with an pMDI device had higher adherence rates, better health outcomes and lower health costs for the Spanish National Health System.

##### PMD103

##### THERAPY ADHERENCE IN PATIENTS WITH MULTIPLE SCLEROSIS USING AN ELECTRONIC MULTIDOSE AUTO-INJECTION DEVICE

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**OBJECTIVES:** Long-term treatment adherence of patients with multiple sclerosis (MS) treated with injectable drugs is a general concern. Closely monitoring patients' therapy adherence may be beneficial. The objective of this study was to assess treatment adherence of MS patients treated with the injectable drug interferon beta-1a, administered with the RebiSmart system. **METHODS:** A retrospective observational study was conducted, monitoring patients' treatment adherence with the RebiSmart system in their normal treatment setting. The RebiSmart is an electronic, multidose auto-self-injection device aimed to improve assessment of treatment adherence. It contains a cartridge including a weekly dose. The device can accurately record time and dosage of each administered injection. Patients can view their own dosing log. Moreover, patients' physicians can download the information providing an objective record of treatment adherence. To determine treatment adherence with RebiSmart, anonymous patient-level data of Dutch and German patients were extracted from the RebiSmart systems on dosing, time, and number of administrations over a five-year time-period. Adherence was defined as taking  $>80\%$  of the treatment doses according to the schedule the doctor prescribed. **RESULTS:** Data was collected from 1832 patients (81% German, 73% females, average age 40.1 years). In total, 95% of the cartridges were used completely, indicating low drug spillage. Over the complete observational period, 91% of all doses were administered according to doctor's prescription. Examining individual adherence, 83% of the patients were considered adherent the whole period using interferon beta-1a. Results from Dutch and German patients were similar. **CONCLUSIONS:** Patients using the RebiSmart device in this study had a considerably higher adherence level than the approximately 60% adherence indicated by previous research studying adherence of MS patients on disease-modifying drugs. Drug spillage was low. Using an auto-injection device monitoring patients' treatment behavior may positively contribute to treatment adherence. This should be further investigated in comparative research.

##### PMD104

##### IDENTIFICATION OF FACTORS INVOLVED IN MEDICATION COMPLIANCE: INCORRECT INHALER TECHNIQUE OF ASTHMA TREATMENT LEADS TO POOR COMPLIANCE

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**OBJECTIVES:** To identify the impact of delivery device of inhaled corticosteroids and long-acting  $\beta_2$ -agonist (ICS/LABA) on asthma medication compliance, and investigate other factors associated with poor compliance. **METHODS:** We conducted a retrospective and multicentre study based on a review of medical registries of asthmatic patients treated with ICS/LABA combinations ( $n=2,213$ ) whose medical devices were either dry powder inhalers (DPI) or pressurized metered-dose inhalers (pMDI). Medication compliance included persistence outcomes through 18 months and medication possession ratios. Data on potential confounders of treatment compliance such as asthma exacerbations, comorbidities, demographic characteristics and healthcare resource utilization were also explored. **RESULTS:** The probability of asthma medication compliance in case of DPI was lower compared to pMDI, which suggest that inhaler devices condition inhalation therapies. There were additional confounding factors that were considered as explanatory variables of compliance. A worse measure of airflow obstruction (FEV1), comorbidities and visiting the GP more than once per month decreased the probability of compliance. Within comorbidities, alcoholism was positively associated with compliance. Patients of 29-39, 40-50 and 51-61 age groups or suffering from more than 2 exacerbations during the study period were more likely to comply with their medication regime. We identified differences among DPI devices and Accuhaler® device impacted negatively greater on compliance compared to other DPIs. We found that GP consultations reduced the probability of medication compliance for patients treated with Formoterol/